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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/774,127	02/06/2004	James M. Brugger	53951-119	8396
21890	7590	10/23/2006	EXAMINER	
PROSKAUER ROSE LLP PATENT DEPARTMENT 1585 BROADWAY NEW YORK, NY 10036-8299			KIM, SUN U	
			ART UNIT	PAPER NUMBER
			1723	

DATE MAILED: 10/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/774,127

Applicant(s)

BRUGGER ET AL.

Examiner

John Kim

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 August 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4,6,7,9 and 21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-2, 4, 6-7, 9, 21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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1. In order to avoid abandonment, the drawing informalities noted in the paper mailed on 1/17/06 described in PTO-948, must now be corrected. Correction can only be effected in the manner set forth in the above noted paper.

2. Claim 21 is objected to because of the following informalities: "exist" on line 12 should be corrected to "exits". Appropriate correction is required.

3. Claim 21 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Recitation of "a dilution inlet directly connected to the blood outlet headspace with no intervening tubular connections between the blood outlet headspace and either of the blood outlet and the dilution inlet" was not described in the specification.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-2, 4, 6-7, 9 and 21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 is indefinite for failing to particularly point out on line 9 that a gap is between a filter media and an outlet cap instead of between "the filter" and the outlet gap. Claim 4 is indefinite for failing to particularly point out which cap is "the cap" on line 1. Is the cap an inlet cap or an outlet cap or both? Claim 21 is indefinite for failing to particularly point out which headspace is "the headspace" on line 6. Is the headspace a blood inlet headspace or a blood outlet headspace or both?

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6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-2, 4, 6-7 and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 4,784,768 (hereinafter referred to as Mathieu). Mathieu teaches a filter apparatus comprising a cylindrical housing (1) having removably attached inlet and outlet end caps (2, 2a) wherein each end cap has two ports (3 or 3a, 12) located radially adjacent to each other for entry or removal of medium or fluid; capillary fiber bundle (4, 5) separates filtrate chamber (10) from the internal lumens of capillary fiber bundle (4, 5) e.g. blood portion of the housing; and an outlet (11) is connected to the filtrate chamber (10) wherein a gap (9) between filter media (4, 5) and the outlet cap (2a) forms a headspace and the outlet cap (2a) has an outlet port (3a) and additional port (12) that are open directly to the headspace (see figure 1-3; col. 5, line 63 – col. 7, line 43). Use of the ports as an inlet and/or outlet for different fluids are an intended use of the apparatus and these are not given patentable weight to the structural limitation without the positive recitation of the specific fluid source e.g. replacement fluid, blood, ultrafiltrate connected to specific ports.

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mathieu.

Mathieu teaches a filter comprising a housing (1) having a blood volume and a treatment fluid volume separated by a filter membrane consisting substantially of filter fibers (4, 5) that exit commonly into an inlet and an outlet headspaces (8, 9) partly defined by respective caps (2, 2a) with inlet (3) and outlet (3a), a dilution inlet (12) directly connected to the outlet (3a) leading to the outlet headspace (9) (see Fig. 1; col. 5, line 63 – col. 7, line 43). Claim 21 essentially differs from the filter of Mathieu in reciting that a dilution inlet directly connected to the blood outlet headspace with no intervening tubular connections between the blood outlet headspace and either of the blood outlet and the dilution inlet. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the filter of Mathieu to provide direction connection of the dilution inlet to the outlet headspace, since it has been held that rearranging parts of an invention involves only routine skill in the art. In re Japikse, 86 USPQ 70.

10. Applicant's arguments with respect to claims 1-2, 4, 6-7, 9 and 21 have been considered but are moot in view of the new ground(s) of rejection. Applicants argue that Mathieu does not

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have “both the outlet port for blood and the infusion port being connected to the housing such that they open directly to said headspace”. However, Mathieu does teach that the outlet port (3a) and additional port (12) connected to the outlet port (3a) open directly to the headspace (9) (see Fig. 1).

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

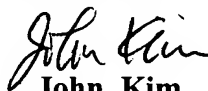
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to John Kim whose telephone number is 571-272-1142. The examiner can normally be reached on Monday-Friday 7 a.m. - 3:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John Kim can be reached on 571-272-1142. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



John Kim
Primary Examiner
Art Unit 1723

JK

October 16, 2006